activity has/have, in the judgment of the Administrator, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(f) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

(g) Following initial evaluation of the protocol by Agency staff, EPA shall submit the protocol and all supporting materials, together with the staff evaluation, to the Human Studies Review Board.

(h) EPA must provide the submitter of the proposal copies of the EPA and Human Studies Review Board reviews.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78 FR 10544, Feb. 14, 2013 and amended at 78 FR 10544, Feb. 14, 2013]

§ 26.1604 EPA review of completed human research.

(a) When considering, under any regulatory statute it administers, data from completed research involving intentional exposure of humans to a pesticide, EPA must thoroughly review the material submitted under § 26.1303, if any, and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall notify the submitter of the research of the results of the EPA and Human Studies Review Board reviews.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78 FR 10544, Feb. 14, 2013 and amended at 78 FR 10545, Feb. 14, 2013]

§ 26.1605 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) *Membership.* The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) *Responsibilities.* The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78 FR 10544, Feb. 14, 2013]

§ 26.1606 Human Studies Review Board review of proposed human research.

In commenting on proposals for new research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the proposed research, including all elements required in § 26.1603(b) and (c) and any additional

conditions recommended pursuant to § 26.1603(d).

[78 FR 10545, Feb. 14, 2013]

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the completed research, and must apply the appropriate standards in subpart Q of this part.

[78 FR 10545, Feb. 14, 2013]

Subpart Q—Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1701 To what does this subpart apply?

(a) For decisions under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a), this subpart applies to research involving intentional exposure of human subjects to any substance.

(b) For decisions under any regulatory statute administered by EPA other than those statutes designated in paragraph (a) of this section, this subpart applies to research involving intentional exposure of human subjects to a pesticide.

[78 FR 10545, Feb. 14, 2013]

§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 also apply to this subpart.

[78 FR 10545, Feb. 14, 2013]

§ 26.1703 Prohibitions applying to all research subject to this subpart.

(a) Prohibition of reliance on scientifically invalid research. EPA must not rely on data from research subject to this subpart unless EPA determines that the data are relevant to a scientific or policy question important for EPA decisionmaking, that the data were derived in a manner that makes them scientifically valid and reliable, and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA must consider:

(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted.

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question.

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data.

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research subject to this subpart involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children. Except as provided in § 26.1706, EPA must not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[78 FR 10545, Feb. 14, 2013]

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults.

(a) This section applies to research subject to this subpart that is not subject to § 26.1705.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section if there is clear and convincing evidence that:

(1) The conduct of the research was fundamentally unethical (*e.g.*, the research was intended to seriously harm participants or failed to obtain informed consent); or

(2) The conduct of the research was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at